



DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 205

[Document Number AMS-NOP-17-0080; NOP-17-09]

RIN 0581 AD78

National Organic Program: Amendments to the National List of Allowed and Prohibited Substances for 2017 NOSB Recommendations (Livestock and Handling)

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This final rule amends the National List of Allowed and Prohibited Substances (National List) section of the United States Department of Agriculture's (USDA's) organic regulations to implement recommendations submitted to the Secretary of Agriculture (Secretary) by the National Organic Standards Board (NOSB). This rule adds elemental sulfur to the National List for use in organic livestock production and reclassifies potassium acid tartrate from a non-agricultural substance to an agricultural substance and requires the organic form of the ingredient when commercially available. This rule also corrects the amendatory instructions to ensure proper placement of the regulatory text.

DATES: This final rule is effective [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Robert Pooler, Standards Division, National Organic Program. Telephone: (202) 720-3252.

SUPPLEMENTARY INFORMATION:

I. Background

On December 21, 2000, the Secretary established the National List within part 205 of the USDA organic regulations (7 CFR 205.600 through 205.607). The National List identifies the synthetic substances that may be used and the nonsynthetic (natural) substances that may not be used in organic production. The National List also identifies synthetic, nonsynthetic nonagricultural, and nonorganic agricultural substances that may be used in organic handling. The Organic Foods Production Act of 1990, as amended, (7 U.S.C. 6501- 6522) (OFPA), and § 205.105 of the USDA organic regulations specifically prohibit the use of any synthetic substance in organic production and handling unless the synthetic substance is on the National List. Section 205.105 also requires that any nonorganic agricultural and any nonsynthetic nonagricultural substance used in organic handling be on the National List. Under the authority of OFPA, the National List can be amended by the Secretary based on recommendations presented by the NOSB. Since the final rule establishing the National Organic Program (NOP) became effective on October 21, 2002, USDA's Agricultural Marketing Service (AMS) has published multiple rules amending the National List.

This final rule amends the National List to implement NOSB recommendations on two amendments to the National List that were submitted to the Secretary on November 2, 2017. The amendments in this final rule are discussed in the section on Overview of Amendments below.

II. Overview of Amendments

The following provides an overview of the amendments to designated sections of the National List regulations. The background information on each substance and the

basis for the NOSB recommendation were addressed in the proposed rule (83 FR 18744) and have not been included in this final rule. The NOSB evaluated each substance by applying the OFPA substance evaluation criteria to determine if the substance is compatible with organic production and handling. For each substance, AMS reviewed the recommendation submitted to the Secretary to determine if the OFPA evaluation criteria had been appropriately applied and whether the addition to or amendment of the National List would not supersede other federal regulations. Our review determined that the substances described in this final rule meet these conditions. Therefore, AMS accepted each NOSB recommendation and initiated this rulemaking.

AMS received five comments on the proposed rule. After considering the received comments, AMS has determined that the addition of elemental sulfur to the National List for organic livestock production and amendment of potassium acid tartrate described in the proposed rule will be finalized without change. Section E of this final rule provides an overview of the received comments and AMS's response to these comments.

§ 205.603 Synthetic substances allowed for use in organic livestock production.

This final rule adds one substance, elemental sulfur, to § 205.603, synthetic substances allowed for use in organic livestock production.

Elemental Sulfur

This final rule amends § 205.603(b) of the National List to add elemental sulfur for use as a parasiticide to treat livestock and livestock housing as paragraph (b)(2). Elemental sulfur is added to the National List as a topical pesticide treatment in organic livestock production to repel mites, fleas, and ticks from livestock and livestock living

quarters. Mites, fleas, and ticks are vectors of livestock diseases and may heavily infest livestock and livestock living quarters. Elemental sulfur is dusted on and rubbed into the feathers and hair of livestock and applied to interior surfaces of livestock housing. Elemental sulfur is also on the National List for use in organic crop production as an insecticide (including mite control), § 205.601(e); as a plant disease control, § 205.601(i); and as a plant or soil amendment, § 205.601(j). Organic livestock or poultry producers can use elemental sulfur as a topical treatment when preventive practices are inadequate to prevent mite, flea, or tick infestation. When organic livestock producers plan to use elemental sulfur as a topical pest control, certifying agents must ensure that preventive pest control practices along with the possible use of elemental sulfur are included in the producer's organic system plan. Agents must also verify implementation of preventive practices before approving the use of elemental sulfur during onsite inspection.

§ 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”

This rule removes one substance, potassium acid tartrate, from § 205.605 and relists this substance in § 205.606.

Potassium acid tartrate

This final rule amends the National List to reclassify potassium acid tartrate from a nonagricultural substance listed in § 205.605(b) to an agricultural substance listed in § 205.606(q).

Potassium acid tartrate is currently allowed as a synthetic substance for use in organic handling. Potassium acid tartrate has been on the National List in § 205.605(b)

since October 2002. A 2017 technical report reviewed by the NOSB indicates that potassium acid tartrate is a byproduct of the wine making process and is extracted with water. Based upon this information, the NOSB during its October 31 – November 2, 2017 meeting recommended reclassifying potassium acid tartrate as an agricultural substance and moving it to § 205.606 of the National List. This amendment to the USDA organic regulations requires organic handlers who use potassium acid tartrate to source an organic form of the ingredient. Only when organic potassium acid tartrate is not commercially available¹ can nonorganic potassium acid tartrate be used in organic handling. When certifying agents review handling organic system plans that include the use of potassium acid tartrate, they must ensure that organic potassium acid tartrate is used unless it is documented that organic potassium acid tartrate is not commercially available. Sourcing of potassium acid tartrate must also be verified during inspection.

III. Related Documents

The NOSB proposal to add elemental sulfur to the National List and to re-designate the listing of potassium acid tartrate as a non-organic agricultural product on the National List was published on April 30, 2018. In addition, on May 30, 2017, a Notice was published in the Federal Register (82 FR 24659) announcing the fall 2017 NOSB meeting. One purpose of the meeting was to deliberate on substances either petitioned or recommended as amendments to the National List.

IV. Statutory and Regulatory Authority

The OFPA authorizes the Secretary to make amendments to the National List based on recommendations developed by the NOSB. Sections 6518(k) and 6518(n) of

¹ See 7 CFR 205.606 and 7 CFR 205.2 for definition of “Commercially available.”

the OFPA authorize the NOSB to develop recommendations for submission to the Secretary to amend the National List and establish a process by which persons may petition the NOSB for the purpose of having substances evaluated for inclusion on or deletion from the National List. Section 205.607 of the USDA organic regulations sets forth the National List petition process. The current petition process (81 FR 12680, March 10, 2016) can be accessed through the NOP Program Handbook on the NOP Web site at <https://www.ams.usda.gov/rules-regulations/organic/handbook>.

A. Executive Orders 12866 and 13771, and Regulatory Flexibility Act.

This rulemaking falls within a category of regulatory actions that the Office of Management and Budget (OMB) has exempted from Executive Order 12866.

Additionally, because this final rule does not meet the definition of a significant regulatory action, it does not trigger the requirements contained in Executive Order 13771. *See* OMB's Memorandum titled "Interim Guidance Implementing Section 2 of the Executive Order of January 30, 2017, titled 'Reducing Regulation and Controlling Regulatory Costs'" (February 2, 2017).

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601-612) requires agencies to consider the economic impact of each rule on small entities and evaluate alternatives that would accomplish the objectives of the rule without unduly burdening small entities or erecting barriers that would restrict their ability to compete in the market. The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to the action. Section 605 of the RFA allows an agency to certify a rule, in lieu of preparing an analysis, if the rulemaking is not expected to have a significant economic impact on a substantial number of small entities.

The Small Business Administration (SBA) sets size criteria for each industry described in the North American Industry Classification System (NAICS), to delineate which operations qualify as small businesses. The SBA has classified small agricultural producers that engage in crop and animal production as those with average annual receipts of less than \$750,000. Handlers are involved in a broad spectrum of food production activities and fall into various categories in the NAICS Food Manufacturing sector. The small business thresholds for food manufacturing operations are based on the number of employees and range from 500 to 1,250 employees, depending on the specific type of manufacturing. Certifying agents fall under the NAICS subsector, “All other professional, scientific and technical services.” For this category, the small business threshold is average annual receipts of less than \$15 million.

AMS has considered the economic impact of this rulemaking on small agricultural entities. Data collected by the USDA National Agricultural Statistics Service (NASS) and the NOP indicate most of the certified organic production operations in the U.S. would be considered small entities. According to the 2016 Certified Organic NASS Survey, 13,954 certified organic farms in the U.S. reported sales of organic products and total farm gate sales in excess of \$7.5 billion.² Based on that data, organic sales average \$541,000 per farm. Assuming a normal distribution of producers, we expect that most of these producers would fall under the \$700,000 sales threshold to qualify as a small business.

² U.S. Department of Agriculture, National Agricultural Statistics Service. September 2017. Certified Organic Survey, 2016 Summary. http://usda.mannlib.cornell.edu/usda/current/OrganicProduction/OrganicProduction-09-20-2017_correction.pdf.

According to the NOP's Organic Integrity Database there are 9,633 certified handlers in the U.S.³ The Organic Trade Association's 2017 Organic Industry Survey has information about employment trends among organic manufacturers. The reported data are stratified into three groups by the number of employees per company: Less than 5; 5 to 49; and 50 plus. These data are representative of the organic manufacturing sector and the lower bound (50) of the range for the larger manufacturers is significantly smaller than the SBA's small business thresholds (500 to 1,250). Therefore, AMS expects that most organic handlers would qualify as small businesses.

The USDA has 80 accredited certifying agents who provide organic certification services to producers and handlers. The certifying agent that reports the most certified operations, nearly 3,500, would need to charge approximately \$4,200 in certification fees in order to exceed the SBA's small business threshold of \$15 million. The costs for certification generally range from \$500 to \$3,500, depending on the complexity of the operation. Therefore, AMS expects that most of the accredited certifying agents would qualify as small entities under the SBA criteria.

The economic impact on entities affected by this rule would not be significant. The effect of this rule, if implemented as final, would be to allow the use of additional substances in organic crop or livestock production and organic handling. This action would increase regulatory flexibility and would give small entities more tools to use in day-to-day operations. AMS concludes that the economic impact of this addition, if any, would be minimal and beneficial to small agricultural service firms. Accordingly, USDA

³ Organic Integrity Database: <https://organic.ams.usda.gov/Integrity/>. Accessed on March 23, 2018.

certifies that this rule would not have a significant economic impact on a substantial number of small entities.

B. Executive Order 12988.

Executive Order 12988 instructs each executive agency to adhere to certain requirements in the development of new and revised regulations in order to avoid unduly burdening the court system. This final rule is not intended to have a retroactive effect. Accordingly, to prevent duplicative regulation, states and local jurisdictions are preempted under the OFPA from creating programs of accreditation for private persons or state officials who want to become certifying agents of organic farms or handling operations. A governing state official would have to apply to USDA to be accredited as a certifying agent, as described in section 6514(b) of the OFPA. States are also preempted under sections 6503 through 6507 of the OFPA from creating certification programs to certify organic farms or handling operations unless the state programs have been submitted to, and approved by, the Secretary as meeting the requirements of the OFPA.

Pursuant to section 6507(b)(2) of the OFPA, a state organic certification program that has been approved by the Secretary may, under certain circumstances, contain additional requirements for the production and handling of agricultural products organically produced in the state and for the certification of organic farm and handling operations located within the state. Such additional requirements must (a) further the purposes of the OFPA, (b) not be inconsistent with the OFPA, (c) not be discriminatory toward agricultural commodities organically produced in other States, and (d) not be effective until approved by the Secretary.

In addition, pursuant to section 6519(c)(6) of the OFPA, this final rule would not supersede or alter the authority of the Secretary under the Federal Meat Inspection Act (21 U.S.C. 601-624), the Poultry Products Inspection Act (21 U.S.C. 451-471), or the Egg Products Inspection Act (21 U.S.C. 1031-1056), concerning meat, poultry, and egg products, respectively, nor any of the authorities of the Secretary of Health and Human Services under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 et seq.), nor the authority of the Administrator of the Environmental Protection Agency under the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136 et seq.).

C. Paperwork Reduction Act.

No additional collection or recordkeeping requirements are imposed on the public by this rule. Accordingly, OMB clearance is not required by the Paperwork Reduction Act of 1995, 44 U.S.C. 3501, Chapter 35.

D. Executive Order 13175.

This final rule has been reviewed in accordance with the requirements of Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. The review reveals that this regulation will not have substantial and direct effects on tribal governments and will not have significant tribal implications.

E. Comments Received on Proposed Rule AMS-NOP-17-0080;NOP-17-09.

During a 60-day comment period that closed on June 29, 2018, AMS received five comments on proposed rule AMS-NOP-17-0080. These comments were submitted by a certifying agent, a dairy producers' association, an egg producer, a trade association, and a dairy operation. The received comments can be viewed at <https://www.regulations.gov/> by searching for the document AMS-NOP-17-0080.

Comments received on additions to § 205.603

All comments received by AMS indicated support for the addition of elemental sulfur to § 205.603(b) for use as an external parasiticide to treat organic livestock and poultry for the control of mites, fleas, and ticks when preventive practices are ineffective. The certifying agent's comment noted that elemental sulfur is effective when dusted on or rubbed into the feathers of poultry or hair of livestock and applied to appropriate surfaces of livestock housing. The egg producer stated that elemental sulfur is the only effective substance for removing or repelling mite infestation in cage-free poultry. The dairy operation commented that elemental sulfur works as a repellent to mites, fleas, and ticks that may be vectors of disease that can be transmitted to livestock. The comment from the membership-based trade association supported adding elemental sulfur to the National List for topical pest control since current available alternative topical control substances are limited to specific livestock species, such as dairy, or have limited efficacy in controlling lice or mites. Comments on elemental sulfur did not propose amending the elemental sulfur annotation to further restrict its application when use in organic production. Also, AMS did not receive comments that opposed the addition of elemental sulfur to § 205.603.

Comments received on amendment to § 205.606

AMS received only one comment on reclassifying potassium acid tartrate, also known as cream of tartar, as a synthetic substance listed in § 205.605 to a nonorganic agricultural substance included in § 205.606. In its comment, the member-based trade association noted that potassium acid tartrate's prior classification as a synthetic nonagricultural substance in § 205.605 was not accurate given that potassium acid tartrate

is produced through mechanical and natural processes utilizing hot water, filtering, cooling and precipitation associated with the winemaking process. The trade association also stated that the reclassification of potassium acid tartrate to § 205.606 provides incentive for the development of organic potassium acid tartrate, because organic sources for this substance are currently scarce given the limited production of USDA certified organic wine.

AMS Response to Comments

AMS agrees with the received comments supporting the addition of elemental sulfur to § 205.603 and the reclassification of potassium acid tartrate for § 205.605 to § 205.606. AMS determined that the addition of elemental sulfur to the National List as a topical livestock treatment and the reassignment of potassium acid tartrate as a non-organic agricultural product met the OFPA substance evaluation criteria. AMS also determined that these amendments to the National List did not supersede other federal regulations. The comments received on the proposal supported the amendments and did not provide any basis for reconsidering the amendments. Consequently, this final rule makes no changes to the respective listings that were described in the proposed rule.

On December 27, 2018, AMS published a rule amending §§ 205.603 and 205.606, effective January 28, 2019 (83 FR 66559). Therefore, the amendatory instructions in this final rule have been updated from those set out in the proposed rule that was published April 30, 2018.

F. General Notice of Public Rulemaking.

This final rule reflects recommendations submitted by the NOSB to the Secretary to add one substance to the National List and to reclassify one substance on the National List.

List of Subjects in 7 CFR Part 205

Administrative practice and procedure, Agriculture, Animals, Archives and records, Imports, Labeling, Organically produced products, Plants, Reporting and recordkeeping requirements, Seals and insignia, Soil conservation.

For the reasons set forth in the preamble, 7 CFR part 205, subpart G, is amended as follows:

PART 205—NATIONAL ORGANIC PROGRAM

1. The authority citation for 7 CFR part 205 continues to read as follows:

Authority: 7 U.S.C. 6501 – 6522.

2. Amend § 205.603 by redesignating paragraphs (b)(2) through (10) as (b)(3) through (11) and adding new paragraph (b)(2) to read as follows:

§ 205.603 Synthetic substances allowed for use in organic livestock production.

* * * * *

(b) * * *

(2) Elemental sulfur—for treatment of livestock and livestock housing.

* * * * *

§ 205.605 [Amended]

3. Amend § 205.605(b) by removing “Potassium acid tartrate.”
4. Amend § 205.606 by redesignating paragraphs (q) through (v) as (r) through (w) and adding new paragraph (q) to read as follows:

**§ 205.606 Nonorganically produced agricultural products allowed as ingredients in
or on processed products labeled as “organic.”**

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(q) Potassium acid tartrate.

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Dated: April 25, 2019.

Bruce Summers,
Administrator,
Agricultural Marketing Service.

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